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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/699,652	10/30/2000	Edgar B. Cahoon	BB1168 US NA	8593

7590 09/25/2003

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[REDACTED] EXAMINER

MCELWAIN, ELIZABETH F

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1638

DATE MAILED: 09/25/2003

LH

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/699,652	CAHOON ET AL.
	Examiner	Art Unit
	Elizabeth F. McElwain	1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 June 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 16-21,25-29 and 38-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 16-21,25-29 and 38-40 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 27 June 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6/27/03.
- 4) Interview Summary (PTO-413) Paper No(s) _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

The amendment filed June 27, 2003 has been entered.

Claims 1-15, 22-24 and 30-37 are cancelled.

Claim 39 is newly amended.

Claims 16-21, 25-29 and 38-40 are pending and are examined.

5 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10 Claims 16-21, 25-29 and 38-40 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility, a credible asserted utility or a well established utility, as stated in the last office action.

Claims 16-21, 25-29 and 38-40 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, as stated in the last office action.

15 Applicants' arguments filed June 27, 2003 have been fully considered but they are not persuasive. Applicants argue that the rejection should be withdrawn given that SEQ ID NO: 14 contains the features of TGL described by Brady et al., which are a trypsin-like catalytic triad, a W₈₈ that is the center of a long loop called a "lid" for the catalytic center, and a conserved motif having an active S in the conserved motif (G-X-S-X-G). Applicants assert that a Blast search 20 using SEQ ID NO: 14 resulted in the 10 best "hits" being lipases, that 7 of the 10 tested positive for lipase activity, and that of the 7, 5 are TGLs and 2 are lysosomal acid lipases. Therefore,

applicants state that the claimed sequences are similar to polypeptides with lipase activity, and thus has utility. Applicants further state that for all of these reasons and based on the Brady and Carriere references that the specification meets the requirements for a well established and a credible utility and that one of ordinary skill in the art would have immediately recognized the 5 utility and known how to use the claimed invention.

The Examiner maintains that the rejection is proper given that while the catalytic triad is suggestive of a TGL, the positions of the three amino acids differ from those in the known TGL. In addition, the W₈₈ is at a different position and it is unclear what constitutes the long loop called a "lid". In addition, it appears that the conserved motif (G-X-S-X-G) is present in other classes of 10 lipases that are not TGLs, so that by the presence of this motif one cannot conclude that it is a TGL. Furthermore, applicants' own results show that there is uncertainty with regard to the specific type of lipase activity of SEQ ID NO: 14, and indicate that there was a similar level of homology with TGLs and lysosomal lipases. In addition, it is unclear what is meant by the statement that of the 10 best "hits", 7 of the 10 tested positive for lipase activity. Mere assertions 15 of the activities of the sequences obtained from the BLAST search are not sufficient to identify the activity of the claimed sequences. Therefore, the specification does not support a credible or well established utility.

Claims 16-21, 25-29 and 38-40 are rejected under 35 U.S.C. 112, first paragraph, as 20 containing subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated in the last office action.

Applicants' arguments filed June 27, 2003 have been fully considered but they are not persuasive. Applicants argue that the rejection should be withdrawn in view of the reasons set forth above with regard to the rejection under 101, stating that the invention is enabled by the structural features disclosed by Brady et al together with the similarity of SEQ ID NO: 14 to lipases as shown in the BLAST results. In addition, applicants argue that "the Utility Guidelines expressly allow for utility to be established solely on homology data" in Example 10, and that working examples are not required.

The Examiner maintains that the specification does not teach one skilled in the art how to use the claimed invention, as stated above. The Examiner disagrees that the structural features disclosed by Brady et al together with the similarity of SEQ ID NO: 14 to lipases as shown in the BLAST results is sufficient evidence that SEQ ID NO: 14 can be used as a TGL, as stated previously. Furthermore, the claims are not limited to those sequences that have these structural characteristics. In addition, Example 10 provided in the Utility Guidelines does not provide that utility may be established solely on homology data in all instances. In Example 10, the claimed sequence is 95% identical to known lipases. Therefore, the example provides a situation where the claimed nucleic acid has high homology to a general class of enzymes that are well characterized, while in the present case the homology is low at about 32-34% identity to TGLs, which have a specific type of lipase activity. In addition, the claims are drawn not only to SEQ ID NO: 14, but to any sequence that has 80% identity to SEQ ID NO: 14. Thus, it would require

undue experimentation by one skilled in the art to make and/or use a nucleic acid encoding a TGL having at least 80% identity to SEQ ID NO: 14.

No claims are allowed.

5 **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after 10 the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM.

20 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

25 Any inquiry of a general nature or relating to the status of this application should be directed to the legal analyst, Tiffany Tabb, whose telephone number is (703) 605-1238, or to the Group receptionist whose telephone number is (703) 308-0196.

Serial No. 09/699,652
Art Unit 1638

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Elizabeth F. McElwain, Ph.D.
September 22, 2003

Elizabeth F. McElwain
ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600